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LONG-TERM (FIVE-YEAR) CLINICAL EVALUATION OF THE RESOLUTE CORONARY ZOTAROLIMUS-ELUTING STENT: THE RESOLUTE US CLINICAL TRIAL

Poster Contributions

Poster Hall B1

Sunday, March 15, 2015, 9:45 a.m.-10:30 a.m.

Session Title: Peripheral and Vascular Biology

Abstract Category: 34. TCT@ACC-i2: Coronary Intervention: Devices

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Background: Limited 5-year outcomes are available with second-generation drug eluting stents, including the Resolute zotarolimus-eluting stent (R-ZES). Long-term data is particularly important in patients with diabetes mellitus (DM), who may have increased delayed or recurrent clinical events.

Methods: The RESOLUTE US (R-US) trial enrolled patients with de novo coronary lesions (lesion length ≤ 27 mm, vessel size > 2.25 mm in one- or two-vessel treatment), with FDA-mandated annual clinical follow-up (FU), and CEC adjudication of all clinical events. Patients with DM were a pre-specified subset in the "main cohort" (2.5 to 3.5 mm diameter stents).

Results: A total of 1402 patients (1,573 lesions), including 1112 patients (1221 lesions) in the main cohort were enrolled. 34% had DM, 75% were treated for type B2/C lesions, and 10% received two-vessel treatment. At 4 years, the cumulative incidence of target lesion failure (TLF) was 10.1%; including clinically-driven target lesion revascularization (TLR) in 5.3%, target vessel myocardial infarction (TV-MI) in 2.6%, cardiac death in 2.9%, and ARC def/prob stent thrombosis (ST) in 0.4%. Between 1 and 4 years (late FU), TLF was 5.2%, TLR 2.3%, TV-MI 1.2%, cardiac death 2.2%, and ARC def/prob ST 0.2%. Dual antiplatelet therapy was used in 93.8% and 51.4% of patients at 1 and 4 years, respectively. There were no differences in any of the outcomes between patients with DM (N=374) vs. without DM (N=738) at any time point in the main cohort. Five-year results will be available at ACC 2015.

Conclusion: R-ZES in the R-US trial was associated with (1) excellent clinical outcomes, including very low TLR and ST during late FU, and (2) similar outcomes in patients with DM vs. without DM.